K030830

8.0 510(k) Summary

JUL 15 2003

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2280

Contact: Patricia D. Wilson, Regulatory Affairs Specialist

DEVICE NAME: B. Braun Nerve Block Catheter

COMMON OR USUAL NAME: Nerve Block Catheter / Elastomeric Infusion Pump Accessory

DEVICE CLASSIFICATION: Class II, 21 CFR 868.5120 (Anesthetic Conduction Catheter) and 21 CFR § 880.5725 (Elastomeric Infusion Pump)

PREDICATE DEVICE:

B. Braun Medical Inc. Soft Tip Epidural Catheter Kit (K971233)
B. Braun Medical Inc. Perifix® Set for Epidural Anesthesia with Tuohy Needle and Catheter (K813186)
I-Flow Corporation Nerve Block Infusion Kit (K984502)
I-Flow Corporation Intra Op Catheter (K991543)

DESCRIPTION: The B. Braun Nerve Block Catheter consists of polyamide tubing with an open or closed rounded tip, and will be available in sizes ranging from 18 G to 24 G, with a length ranging from 400 mm to 1010 mm. A soft tip version of the catheter (with a Pebax soft tip welded to the catheter body) will also be available in a closed tip configuration.

INTENDED USE: The B. Braun Nerve Block Catheter is a device intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics near a nerve for regional anesthesia and pain management during the pre-operative, perioperative and postoperative periods associated with general and orthopedic surgery.

SUBSTANTIAL EQUIVALENCE: The B. Braun Nerve Block Catheter has the same materials, method of construction, and similar design as the Perifix® Epidural Catheters that are marketed under the B. Braun Medical Inc. Premarket Notifications K971233 and K813186. The B. Braun Nerve Block Catheter differs from the Perifix Epidural Catheter in the intended use, the location of catheter markings, and the size range.

SUBSTANTIAL EQUIVALENCE (continued):

The indications for the B. Braun Nerve Block Catheter are similar to the indications for the Nerve Block Infusion Kit and the Intra Op Catheter that are marketed by I-Flow Corporation under the Premarket Notifications K984502 and K991543.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Patricia D. Wilson
Regulatory Affairs Specialist
B. Braun Medical Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K030830
Trade/Device Name: B. Braun Nerve Block Catheter
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: CFR
Product Code: II
Dated: June 11, 2003
Received: June 18, 2003

Dear: Ms. Wilson

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K030830

Device Name: **B. Braun Nerve Block Catheter**

Indications For Use:

The B. Braun Nerve Block Catheter is a device intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics near a nerve for regional anesthesia and pain management during the pre-operative, perioperative and postoperative periods associated with general and orthopedic surgery.

Susan Runn

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030830

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)